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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): P31343US

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on December 13, 2006

Signature Hong Do

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Application Number	Filed
10 / 615,566	07/08/2003

First Named Inventor: Nicola Perone

Art Unit	Examiner
3731	Truong, K.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant/inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [x] attorney or agent of record. Registration number 47,559
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

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December 13, 2006
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NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

[x] *Total of 1 forms are submitted.

Application No.: **10 / 615,566**
Inventor: **Dr. Nicola Perone**
Filing Date: **July 8, 2003**

REASONS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW

Claims 1-18 are in the case. Each of the claims stands rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Pat. No. 6,468,284 to Wallace.

However, Applicant submits that the subject matter recited in each of independent claims 1, 5 and 17 patentably distinguishing the claimed invention from the device disclosed in U.S. 6,428,284 to Wallace.

In particular, independent claims 1, 5 and 17 recite the following elements:

Claim 1: "means for measuring electronically the magnitude of the extraction force applied to the fetal head during a vacuum extraction";

Claim 5: "means for measuring the extraction forces exerted on the fetal head, said means contained in said handle grip"; and

Claim 17: "means for measuring the extraction forces on the fetal head".

As seen, the common term between and amongst these clauses is a "means for measuring the extraction forces" applied to the head of the baby while extracting the child during delivery.

In contrast, Applicant submits that Wallace does *not* measure *extraction forces* applied to the fetal head via the vacuum cup, but instead measures (i) the *magnitude of the vacuum pressure* against the fetal head, (ii) the duration of a specific application of the vacuum device (or the cumulative duration based upon multiple applications), and (iii) the number of times traction force is applied to the cup (though *not* the magnitude of the extraction forces), in order to "ameliorate or avoid potentially undesirable effects of the vacuum to the fetal head."

In order to better clarify these important differences, consideration of the following arguments is kindly requested:

First, the distinctions drawn by Applicant are best appreciated if it is kept in mind that the most significant risks of fetal injury in a vacuum-assisted delivery are directly related to: a) the length of time the cup remains on a fetal head (over 15-20 minutes); b) the use of excessive negative pressure under the cup (over 550-600 mmHg); and c) the occurrence of multiple cup detachments ("pop-offs"). Whereas Wallace's disclosure addresses the first two of the above-mentioned risk factors, Applicant's invention has as its primary objective the elimination of cup detachments secondary to excessive traction; the motivation is to prevent the possibility of fetal scalp lacerations and hemorrhagic lesions when "pop-offs" occur, as is well documented in associated medical literature. Only secondarily, the Applicant's invention addresses the risk factor represented by the duration of the cup application, and does so in a totally different way from Wallace, *viz.*, by means of a second alarm which is not part of the extraction apparatus, but of associated computer software (see below).

As far as the respective structures are concerned, in Wallace's disclosure the handle and the cup are structurally integral; in Applicant's claims, the handle and the cup are separate parts, which must be articulated before use. Most importantly, the cup stem is appropriately modified with the addition of a tang especially designed to fit into a rectangular opening, located on the grip housing, so that it can click into place when rotated 90° in either direction (see the Applicant's specification at page 9, lines 4-10.

The fact that in the Applicant's invention the handle and the cup are two separate parts constitutes a point of novelty having a dual purpose. The first is to provide a pull-sensing handle grip that can be easily and quickly detached and then re-attached to any vacuum extractor whose

stem has been appropriately modified (the Office should note here that there are several different vacuum extractors presently in use, each having a different size and shape). The second purpose is to be able to dispose of only the cup and stem assembly after a single use, while keeping the more expensive electronic pull-sensing handle, which can then be re-sterilized and reused, thereby achieving a considerable savings for both the hospital and the patient.

A second notable structural difference is that the Applicant's pull-sensing handle is designed to house the electronics and to apply traction to the cup using a distinct and independent vacuum source. In contrast, Wallace's device consists of a handle grip (Fig.1, 24) and a palm chamber (Fig 1, 20) that slides on guide members (Fig. 1, 22), for the creation of the vacuum under the cup.

With respect to the claimed electronics, and starting with the strain gauge (which is specifically mentioned in the Office Action), in the Applicant's invention the purpose of the gauge is to measure *the magnitude of the traction applied to the cup*, compare it to a preset value (almost equal to the adhesive force under the cup), and to sound an alarm when traction forces approximately equal the preset value. In Wallace's device, however, the purposes of the strain gauge is to simply measure the negative pressure inside the cup (Wallace col. 5, line 50 to col. 7, line 42, the same citation provided by the Office in its first Action), and to provide a traction signal to the microprocessor associated with the timer in order to keep track of the number of times traction is applied (Wallace col. 8, lines 36-37).

Thus, *nowhere* in Wallace is it stated -- or even suggested -- that the purpose of the strain gauge is to measure the magnitude of traction applied by the doctor to the cup (and therefore to the fetal head). To the contrary, Wallace is limited to disclosure of only the measurement of cup

pressure against the fetal head, and fails to recognize the importance of also measuring the extracting forces.

Further evidence that the strain gauge in Wallace's invention is not intended to measure the magnitude of the traction can be reasonably inferred by the absence of any monitoring device designed for that purpose. Instead, Wallace describes the following two monitoring devices: one for the magnitude of the vacuum with a visual display in mmHg, and one to monitor the duration of the cup's application. The absence in Wallace's invention of an electronic monitoring device to measure traction is in clear contrast with the Applicant's invention, where such a device plays a central role. In fact, in the Applicant's invention the traction applied to the cup is measured (in lbs) and displayed in real-time on the computer screen, *i.e.*, while the vacuum-assisted delivery takes place. It should also be noted that Wallace never mentions or implies the inclusion of a monitoring device used for measuring the magnitude of the traction, even in any of the briefly discussed modifications or alternative embodiments of his invention, thus providing additional evidence that this feature is not within the scope of his invention and should not be cited as a basis for rejection in this instance.

Yet another important difference in the electronics relates to the location of the timer used to monitor the duration of cup application. For example, in Wallace's invention the timer is located in the handle grip, and is activated by the application of a vacuum under the cup. In the Applicant's invention, however, the timer (and the alarm, which is typically set to sound when 15 minutes of cup application are exceeded) is part of the computer software, *i.e.*, outside the handle electronics, and is activated by an operator.

Still another difference in the electronics worth noting is the total absence in the Applicant's invention of a vacuum sensor, which, in contrast, plays a primary role in Wallace's device.

In summary, since the Wallace device measures only the *magnitude of the vacuum pressure* exerted by a vacuum cup against the baby's head rather than the *magnitude of extraction forces applied to the cup* as claimed herein, it follows that Wallace remains inappropriate for citation as a grounds of rejection and should now be withdrawn.

Respectfully submitted,

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